



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/733,080

12/11/2003

Pascual Perez

A36102-PCT-USA-A

9528

21003 7590 07/31/2007

BAKER BOTTS L.L.P.
30 ROCKEFELLER PLAZA
44TH FLOOR
NEW YORK, NY 10112-4498

EXAMINER

KUMAR, VINOD

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

07/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/733,080

Applicant(s)

PEREZ ET AL.

Examiner

Vinod Kumar

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/29/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of objections and rejections

1. Office acknowledges the receipt of Applicant's response filed on May 29, 2007. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1-7, and 9-14 are pending. Claims 1-7, and 9-14 are examined on merits in the instant Office action. It is noted that Drawings (Figures 1 and 2) were erroneously objected in the Office action mailed on January 26, 2007. All previous claim objections and rejections not set forth below have been withdrawn in view of claim amendments. This action is made FINAL.

Election/Restriction

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

3. Claim 10 is objected to because of the following informalities:

Claim 10 is objected for misspelling "anthocyan" in line 4.

Claim 10 is objected for not deleting "line" before "a line" in line 2.

Claim amendment filed in the paper of May 29, 2007 necessitated the claim objection.

Claim Rejections - 35 USC § 112

4. Claims 10 and 11 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record stated in the Office action mailed on January 27, 2007. Applicants traverse the rejection in the paper filed on May 29, 2007.

Applicants argue that various original alleles and lines described in claims 10 and 11 are well known in art. Applicants cite few examples to support their arguments (response, page 9, lines 1-7).

Applicant's arguments were fully considered but were not found to be persuasive. It is maintained that it is unclear what the recitation "R-nj::AC" or "R-nj" are being referred to? It is further unclear what is intended? It is suggested to recite full-form of these recitations.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been necessitated due to the claim amendment filed in the paper of May 29, 2007

Claims 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "including the embryo (R-nj::AC allele)", which is confusing since it is

Art Unit: 1638

unclear what the recitation "embryo (R-nj::AC)" is referring to? Is it the embryo which is having "(R-nj::AC) allele"? It is unclear what is intended? Dependent claim 11 is also rejected because it fails to overcome these deficiencies.

Claims 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "Ac located in R-nj chromosomal region", which is confusing since it is unclear how "R-nj chromosomal region" is similar or different from other regions of chromosomes. Furthermore, the metes and bounds of the recitation "located" are unclear and not defined. It is unclear what is intended? Dependent claim 11 is also rejected because it fails to overcome this deficiency.

Claim Rejections - 35 USC § 112

5. Claims 1-7, and 9-14 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for obtaining a transgenic monocotyledon plant containing a gene of interest that is free of ancillary selection marker sequence comprising using mobilizable sequence of Dt, Mu, Ac/Ds or CACTA transposable elements, does not reasonably provide enablement for using mobilizable sequence of *any* transposable element. The claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for the reasons of record stated in the Office action mailed on January 26, 2007. Applicants traverse the rejection in the paper filed on May 29, 2007.

Art Unit: 1638

Applicants argue that Bennetzen does not discuss the activity of mobilizable sequences introduced into a maize line via recombinant DNA technology. Applicants further argue that that claim 1 is specifically directed to an endogenous transposase, and thus Office ignores the clear language of the claims (response, page 10, lines 8-21).

Applicant's arguments were fully considered but were not found to be persuasive. Applicant's attention is drawn to subparagraph (2) of method step (a) of claim 1, wherein the claim recites "operably linked to the mobilizable sequence of a transposon". This implies that claim 1 and claims dependent thereon comprise a method step which encompasses mobilizable sequence derived from any transposon. This also implies that in order to practice the instantly claimed method one should be able to use any mobilizable sequence derived from any transposon. This would encompass mobilizable sequences which would not be recognized by endogenous maize transposases. As discussed through the teachings of Bennetzen that transposable element recognition machinery is host specific and/or host assisted. This implies that mobilizable sequences derived from diverse transposons would not function in maize. It is important to note that the breadth of the claims encompasses mobilizable sequences of any transposon from any source. Thus one skilled in the art would not be able to practice the instantly claimed method using mobilizable sequences derived from any transposon.

In the absence of guidance, it is maintained that undue experimentation would have been required by a skilled artisan at the time claimed invention was made to

determine how to practice the instantly claimed method by using mobilizable sequences derived from any transposable element.

Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 102

6. Claims 1-4 and 6-remain rejected under 35 U.S.C. 102(b) as being anticipated by Perez et al. (PCT, WIPO, Publication No. WO 98/38323, Published September 3, 1998, Applicant's IDS, an English equivalent published as US Patent Application No. US2002/0157129A1 on 24 October 2002) for the reasons of record stated in the Office action mailed on January 27, 2007. Applicants traverse the rejection in the paper filed on May 29, 2007.

Applicants argue that Perez et al. do not teach that the active transposase should or could be located within a phenotypic marker for excision as in the rejected claims. In fact, the transposase coding sequence described in Perez et al. is located near a GUS marker, but not within the marker. Applicants further argue that Ac transposase used in Perez et al. do not contain its 5' end, which includes the Ds element for auto-excision activity (response, last paragraph bridging the pages 13 and 14).

Applicant's arguments were fully considered but were not found to be persuasive. Applicant's attention is drawn to Example 5 (page 7, right column) and Figure 3, wherein it is clearly disclosed that the vector which provided the source of transposase is created by deleting GUS coding region. It is important to note that although the claims are interpreted in light of the specification, limitations from the specification are

Art Unit: 1638

not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The issue is not whether active transposase "should have or could have" located within the phenotypic marker. Rather, the issue is whether, the reference discloses all the elements of active method steps to practice the instantly claimed invention. In the instant case, the reference discloses all the active method steps that are recited in the instant claims 1-4, and 6 to practice the instantly claimed method as discussed in previous Office action and further outlined as above. See *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC Scalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then prior art anticipates the claimed invention.

Accordingly, the rejection is maintained.

7. Claims 1-3 and 6-7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Yoder et al. (PCT, WIPO, Publication No. WO 92/01370, Published February 6, 1992, Applicant's IDS) for the reasons of record stated in the Office action mailed on January 27, 2007. Applicants traverse the rejection in the paper filed on May 29, 2007.

Applicants argue that Yoder et al. fail to disclose the inclusion of an active transposase within a phenotypic marker for excision as required by the rejected claims (response, page 14, lines 13-14).

Applicant's arguments were fully considered but were not found to be persuasive. Applicant's attention is drawn to page 17, lines 34-37; page 18, lines 5-35; pages 38-39,

and in particular claims 1-2, wherein the reference clearly discloses incorporation of transposase (endogenous or recombinant) in the method for obtaining a transgenic maize plant containing a coding sequence of interest which is free of ancillary sequences, such as selection marker sequences.

Accordingly, it is maintained that Yoder et al. anticipated the instantly claimed invention.

Claim Rejections - 35 USC § 103

8. Claims 9 and 13-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Perez et al. (PCT, WIPO, Publication No. WO 98/38323 A, Published September 3, 1998, Applicant's IDS, an English equivalent published as US Patent Application No. US2002/0157129A1 on 24 October 2002 in view of Ishida et al. (Nature Biotechnology, 14(6):745-750, 1996) for the reasons of record stated in the Office action mailed on January 27, 2007. Applicants traverse the rejection in the paper filed on May 29, 2007.

Applicants argue that Perez et al. fail to teach or even suggest the use inclusion of the transposase within a phenotypic marker for excision. Applicants further argue that Perez et al. fail to teach a transposase having auto-excision activity due to the lack of the appropriate 5' sequence necessary for auto excision. Applicants further argue that Ishidia et al. fail to cure the deficiency of Perez et al. (response, page 15, lines 6-11).

Applicant's arguments were fully considered but were not found to be persuasive.

Applicant's attention is specifically drawn to Example 5 (page 7, right column) and Figure 3, wherein the reference clearly teaches incorporating "a transposase" in the method of producing a transgenic plant containing a coding sequence that is free of ancillary selection marker sequence, such as GUS.

It is important to note that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, one of ordinary skill in the art would have arrived at the claimed invention by combining the prior art teachings of Perez et al. and Ishida et al. to arrive at the instantly claimed invention with reasonable expectation of success.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., lack of 5' sequence necessary for auto excision) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, In the instant case, one of ordinary skill in the art would have arrived at the claimed invention by combining the prior art teachings of Perez et al. and Ishida et al. with reasonable expectation of success.

Summary

9. Claims 1-7, and 12-14 remain rejected.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

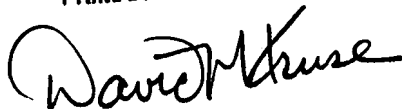
A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is set to expire within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink that reads "David H. Kruse". The signature is written in a cursive, flowing style.